

### REMARKS

Claims 1, 5-10, 12, and 14-21 are pending in this application. Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

#### Interview Summary

On December 1, 2010, the Applicant's representative Mandy Jubang of Occhiuti Rohlicek & Tsao LLP forwarded the following proposed amendment to claim 1 to Examiner Dirk Bass for consideration:

1. (Proposed Amendment) A filter device for the depletion of the leukocyte content from a blood product, comprising  
a housing having an inlet and an outlet and, within said housing, more than two porous elements configured to remove leukocytes, said more than two porous elements each comprising multiple adjacent layers of filtering material having the same filtering and hydrophilicity properties, each of said porous elements including one or more layers of a filtering material and each of said porous elements having a different hydrophilicity,  
said more than two porous elements being arranged in the filter device such that any of said porous elements has a higher hydrophilicity than a successive porous element in a direction of flow, from said inlet to said outlet, of said blood product through said filter device,  
said more than two porous elements including an inlet porous element having a construction of material having a hydrophilicity as measured by a CST or a CWST value of the filtering material that is higher than 63 dyn/cm, and  
a difference between the hydrophilicity of the inlet porous element and a final outlet porous element, as measured by the CST or the CWST value of the filtering material, that is at least 10 dyn/cm.

On December 2, 2010, Examiner Bass and the Applicant's representative Mandy Jubang conducted a telephone interview in which the above proposed amendment to claim 1 was discussed in view of the Bormann and Majurel references of record. The Examiner and the Applicant's representative agreed that additional structural language related to the difference between the hydrophilicity of adjacent porous elements would clarify the claim and more clearly distinguish the Bormann and Majurel references of record.

35 U.S.C. § 103 Rejections

Previously-presented claims 1, 3, 7-10, 12, 16-18, and 20-21 were rejected under 35 U.S.C. § 103(a) as obvious over Bormann et al. (US 6,945,411) in view of Majurel (EP 0542655). Previously-presented claims 4-6, 14, 15, and 19 were rejected under 35 U.S.C. § 103(a) as obvious over Bormann in view of Majurel and further in view of Pall (US 4,925,572), Oka et al. (US 5,298,165), or Heagle et al. (US 5,190,657).

On page 2 of the Advisory Action, the Examiner provided the following comments:

Applicant argues that Bormann does not disclose a filter arrangement that creates a 'hydrophilicity gradient' between successive filter elements. In response, the examiner directs applicant's attention to figure 1 of Bormann where two successive filter elements (REF 1, 2) create a hydrophilicity gradient between said filter elements. Bormann further discloses a filter arrangement having a plurality of filter elements having hydrophilicity gradients between each successive filter element (fig. 2-3). The examiner concedes that Bormann does not disclose such an embodiment where more than two filter elements are used which create an overall 'hydrophilicity gradient' and looks to Majurel to obviate such an omission. Majurel discloses a separation device comprising a filter element having three successive layers, said layers creating a hydrophilicity gradient (abstract). Therefore, the examiner maintains that it would have been obvious to one having ordinary skill in the art to modify the filter element of Bormann to include the multiple layer filter arrangement disclosed in Majurel in order to increase separation efficiency of a filter element.

Based on the above, the Examiner appears to take the following positions: (1) a "filter element" of Bormann can be read as corresponding to a "porous element" of previously-presented claim 1; (2) Majurel's "filter" can be read as corresponding to a "porous element" of previously-presented claim 1; and (3) a "filter element" of Bormann can be modified by the "filter" teachings of Majurel to include three successive layers, said layers creating a hydrophilicity gradient.

As an initial matter, the Applicant notes that while Majurel's filter may be construed as consisting of a composite membrane having three successive layers of

decreasing hydrophilicity, all of the filter embodiments disclosed by Majurel require that the top, most hydrophilic layer be in contact with highly hydrophilic microbeads. See, e.g., Abstract, 2<sup>nd</sup> full paragraph of Majurel (EP 0542 655 A1):

Il comprend au moins un tube capillaire ouvert à son extrémité inférieure, laquelle est munie d'un filtre constitué d'une membrane composite surmontée d'une couche de 2 à 3 mm d'épaisseur de microbilles de verre de diamètre moyen compris entre 20 et 50  $\mu\text{m}$ , ladite membrane composite comprenant les trois couches successives suivantes :

- une première couche très hydrophile, de porosité 5 à 7  $\mu\text{m}$ , au contact des microbilles de verre.
- une seconde couche, intermédiaire, modérément hydrophobe.
- une troisième couche, externe, fortement hydrophobe, percée en son centre d'un orifice d'environ 0,1 mm de diamètre.

and page 2, col. 2, lines 22-42:

Selon une autre caractéristique du dispositif selon l'invention, les microbilles de verre mises en oeuvre présentent un diamètre moyen compris entre 20 et 50 microns, tandis que la membrane composite qui obture le tube capillaire à son extrémité inférieure présente une ouverture de mailles de 5 à 7 microns, autorisant le passage des seuls globules rouges non agglutinés.

Selon une caractéristique additionnelle du dispositif selon l'invention, la membrane composite mise en oeuvre pour obturer le tube capillaire à son extrémité inférieure est constituée des trois couches ci-après :

- une première couche très hydrophile au contact des microbilles.
- une couche intermédiaire modérément hydrophobe
- une couche externe fortement hydrophobe percée en son centre d'un orifice d'environ 0,1mm de diamètre pour l'écoulement du flux de la phase mobile.

Again, and to emphasize, all embodiments of the filter described in Majurel require that the top, most hydrophilic layer be in contact with highly hydrophilic microbeads. Even if, as asserted by the Examiner, it would have been obvious to a skilled person to increase separation efficiency of a filter element of Bormann by implementing that filter element to include three successive layers of decreasing hydrophilicity, a skilled person would have recognized that the required addition of microbeads to each filter element of Bormann and a subsequent arrangement of more than two Majurel-modified Bormann filter elements within a housing of a filter device would have compromised, if not completely eliminated, certain desired effects<sup>1</sup> that result from the structure of the filter device of previously-presented claim 1.

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<sup>1</sup> See, e.g., page 5, 1<sup>st</sup> and 4<sup>th</sup> paragraphs of the application as filed:

"...each porous element comprising one or more layers of filtering material, wherein said at least two porous elements have different hydrophilicity, characterized in that the said porous elements are arranged in the filter device so that the first element has a higher hydrophilicity than the successive filter element (s) in the direction of flow, from inlet to outlet, of the blood product through the filter device; ...

[i]n a preferred embodiment of the invention, the filter device comprises more than two porous elements and the hydrophilicity (CST or CWST) of any given element is higher than the hydrophilicity of its successive element in the direction of flow from inlet to outlet, so as to establish a decreasing hydrophilicity profile (negative gradient)."

See, also, page 8, 5<sup>th</sup> paragraph to page 9, 3<sup>rd</sup> paragraph of the application as filed (emphasis added):

It has been found that in the filter according to the invention the first set (or filter element) of more hydrophilic layers is easily wetted by the liquid and therefore the liquid pressure is distributed evenly on the following more hydrophobic layers. With this filter set-up regional pressure differences because of

The above observations notwithstanding, it is clear from the Majurel teaching that the “three successive layers” (“des trios couches ciaprés”) arrangement of the disclosed filter means that each layer immediately precedes a next layer that has increased hydrophobicity properties. In other words, Majurel completely lacks a filter configuration wherein successive porous elements each comprise a set of layers of filtering material having the same filtering and hydrophilicity properties as the present claims require. To the skilled person reading Majurel, using intervening “layers of filtering material” having the *same* hydrophilicity properties would appear to completely destroy the stated technical effects associated with three successive layers having decreasing hydrophilicity. Accordingly, Applicant considers that the Examiner’s present use, and interpretation, of Majurel is not appropriate and that the skilled person would not identify and apply this reference in a combination with Bormann—at least because the features as recited by amended claim 1 would not be achieved.

In view of the above reasoning, the Applicant respectfully submits that the Examiner’s position in combining the Bormann and Majurel references is not tenable, and further submits that claim 1, as previously-presented, is allowable over the combination of Bormann and Majurel.

However, for the purpose of advancing prosecution and to further clarify the scope of claim 1, the Applicant has amended claim 1 to require a filter device for the depletion of the leukocyte content from a blood product to have a housing within which more than two porous elements are arranged, "said more than two porous elements each

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**gas bubbles attached to the surface of the filter can be prevented**, which decreases the risk of micro-ruptures in the filter.

**The described arrangement improves the air elimination from the filter material, avoiding blood flow channeling, leading to a better leukocyte removal efficiency**; moreover, by better exploiting the whole filtering material, its quantity can be reduced with consequent reduced cell loss.

**A further advantage of a filtration system containing described filter element is that due to the improved wettability of the inlet layer the needed priming pressure as well as the priming time of the filter is reduced.**

**For the same reason the gravity pressure head which is needed for the efficient filtration of the liquid can be reduced.** Therefore the distance needed between the primary bag and the filter element is **smaller** which is **saving both space and tubing material.**

comprising a set of layers of filtering material having the same filtering and hydrophilicity properties," and "a difference between the hydrophilicity of adjacent sets of layers of two successive porous elements, as measured by the CST or the CWST value of the filtering material, that is in a range from 2 dyn/cm to 50 dyn/cm." Support for these amendments can be found, in one example, in the paragraph bridging pages 5 and 6 and the paragraph bridging pages 7 and 9 of the application as filed.

Considering the above discussion, the Applicant wishes to emphasize that the skilled person would immediately understand that Majurel's filter consists of a composite membrane having three successive layers of decreasing hydrophilicity that clearly cannot be read as corresponding to the claimed "porous element ... **comprising a set of layers of filtering material having the same filtering and hydrophilicity properties.**" These two filter arrangements are fundamentally incompatible. Further, the Applicant wishes to emphasize that no embodiment of Bormann's filter device provides for a difference between the hydrophilicity of adjacent sets of layers of two successive porous elements, as measured by the CST or the CWST value of the filtering material, that is in a range from 2 dyn/cm to 50 dyn/cm." At best, col. 8, lines 8-18 of Bormann, states "...one of the elements can have a CWST in the range of from about 58 dynes/cm to about 75 dynes/cm, and another element can have a CWST in the range from about 78 dynes/cm to about 115 dynes/cm," thereby providing a difference that is at least 3 dyn/cm.

Accordingly, no valid combination of Bormann and Majurel can be fairly construed as disclosing the claimed filter device having "more than two porous elements each comprising a set of layers of filtering material having the same filtering and hydrophilicity properties, and each of said porous elements having a different hydrophilicity,... a difference between the hydrophilicity of adjacent sets of layers of two successive porous elements, as measured by the CST or the CWST value of the filtering material that is in range from 2 dyn/cm to 50 dyn/cm," as required in amended claim 1. Furthermore, it is not apparent why the skilled person would be motivated to combine these two references in the first place at least because of the intervening adjacent layers having the same filtering and hydrophilicity properties, which would appear to destroy

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the described technical effects associated with Majurel's strict "successive layer" filter arrangement.

For at least the foregoing reasons, the Applicant submits that amended claim 1 is allowable over Bormann alone, or over any valid combination of Bormann and Majurel.

Independent claims 9 and 20 include features similar to claim 1 and are allowable for at least the same reasons set forth above with respect to claim 1. All of the dependent claims are allowable for at least the same reasons as the claims from which they depend.

### Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The RCE fee in the amount of \$810 and the Petition for Extension of Time fee in the amount of \$490 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 7B901-002US1.

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